



## **DEPARTMENT OF HOMELAND SECURITY**

### **U.S. Customs and Border Protection**

#### **Notice of Issuance of Final Determination Concerning**

#### **Electroencephalogram (EEG) Cutaneous Electrodes**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determination.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of RhythmLink International L.L.C.’s, Electroencephalogram (EEG) Cutaneous Electrodes. Based upon the facts presented, CBP has concluded in the final determination that the last substantial transformation of the Electroencephalogram (EEG) Cutaneous Electrode Product occurs in the United States.

**DATES:** The final determination was issued on May 24, 2019. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within [INSERT 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Robert Dinerstein, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202-325-0132).

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on May 24, 2019, pursuant to subpart B of part 177, Customs and Border Protection (CBP) Regulations (19 CFR part 177, Subpart B), CBP issued a final determination concerning the country

of origin of the Electroencephalogram (EEG) Cutaneous Electrodes which may be offered to the United States Government under an undesignated government procurement contract. This final determination, in HQ H300745, was issued at the request of RhythmLink International, L.L.C. under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP concluded that the assembly and attachment of a lead wire to the U.S. origin Electroencephalogram (EEG) Cutaneous Electrodes by crimping or gluing in China is not a substantial transformation. Therefore, the last substantial transformation of the RhythmLink Electroencephalogram (EEG) Cutaneous Electrode product occurs in the United States.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the *Federal Register* within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

Dated: May 24, 2019.

Craig T. Clark,  
Acting Executive Director,  
Regulations and Rulings,  
Office of International Trade.



**HQ H300745**

**May 24, 2019**

**OT:RR:CTF:VS H300745 RSD**

**CATEGORY:** Origin

David S. Robinson  
Nexsen Pruet, PLLC  
4141 Parklake Avenue  
Suite 200  
Raleigh, NC 27612

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Electroencephalogram (EEG) Cutaneous Electrodes; Substantial Transformation

Dear Mr. Robinson:

This is in response to your letter, dated September 10, 2018, requesting a final determination on behalf of Rhythmlink International, LLC. (Rhythmlink) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (CBP) Regulations (19 C.F.R. Part 177).

This final determination concerns the country of origin of various self-adhesive cutaneous electrode products. As a U.S. importer, Rhythmlink is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination. Samples of three versions of the product have been submitted for our review.

**FACTS:**

Rhythmlink is headquartered in Columbia, North Carolina and manufactures and distributes medical devices. It seeks a country of origin determination for the purposes of United States government procurement for a line of Electroencephalogram (EEG) Electrode products.

An EEG is a test that detects electrical activity in the brain using electrodes attached to the scalp. Doctors use an EEG test to help diagnose certain neurological

conditions, such as epilepsy and sleep disorders. The EEG electrode allows for a physical connection between a patient and medical diagnostic equipment. To use the EEG electrodes, the patient's scalp is cleaned, and the cutaneous electrodes are attached to the patient's skin using a small amount of an adhesive conductive gel or paste, either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation. To accomplish its function, the EEG electrode uses a glass-filled ABS plastic mold with a silver-chloride coating. It is designed and manufactured to specifications as a U.S. Food and Drug Administration (FDA) medical regulated "cutaneous electrode", mainly for the recording of its electrical conductor function. RhythmLink's EEG electrodes are disposable.

The product comes in varying lengths/styles and the end user can customize the color of the connecting wire. The electrodes' function is common to all lengths and is unchanged by the color of the connecting wire. There are three EEG electrode products that have common construction and function: the Disposable Slim Cup, the Disposable Deep Cup, and Disposable Webb.

RhythmLink conducts all engineering and design of the EEG electrodes in the United States. The actual production and manufacture of the cutaneous electrodes is outsourced to a third party subcontractor located in the United States. The single-source manufacturer supplies the finished EEG electrodes to RhythmLink, marked "Country of Origin: USA." The manufacturer must further certify that, "This uniform silver coating applied to precision molded products enhances the mechanical and electrical performance of the finished electrode products so they can meet or exceed applicable AAMI Standards."

The fully assembled, packaged end product for medical use consists of five elements: the cutaneous electrode, the lead wire, a miniscule amount of crimp or glue, a heat shrink tube, and packaging. The subcontractor-supplied cutaneous electrodes are shipped from the United States to China where a lead wire is attached. You state that the lead wire acts as an electrical conductor that transfers low voltage electrical signals from the electrode to medical diagnostic equipment. The lead wire used in the product is a commercially available 26-gauge twisted copper wire comprising 19 strands of 38-gauge copper wire with medical grade PVC covering (in a total of 25 color options). The Korean supplier of this wire, cuts the wire, crimps a socket pin, and attaches a connector to one end of the wire and then ships the wire to China. Neither the wire nor the connectors are proprietary and are common electrical materials.

In China, to support certain optional user preferences, the EEG electrodes are either attached to the lead wire of Korean origin, using a crimp produced in the United States or China. Crimp is a mix of tin, copper and nickel and represents only a tiny portion of the product's cost. Alternatively, the process will utilize a German conductive adhesive glue, which is a mix of silver and epoxy and also represents a very small percentage of the product's cost. The lead wire is crimped or glued to the electrode. The

crimping process takes roughly five seconds (six operators can professionally crimp 6,000 products in a day). The alternative gluing process takes roughly 20 seconds (six operators can professionally glue 1,500 products in a day). Next, a heat shrink from either the United States or Japan is used to cover the joint. The heat shrink tube is an off-the-shelf product from a third party contractor from the United States or Japan that is available in almost 40 different diameters. The product is ultrasonically cleaned and dried (spin and convention drying), a heat shrink cover is added, and the product is inserted into a plastic pouch and cardboard packaging. After the EEG electrodes are shipped back to the United States, the products are subjected to randomized testing and sampling for quality control purposes.

## **ISSUE:**

Where does the last substantial transformation of the adhesive cutaneous EEG product occur for purposes of U.S. Government procurement?

## **LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*) (TAA).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

In reaching its country of origin determinations, the Court of International Trade has examined the essential character of an article to determine whether its identity has been substantially transformed through assembly or processing. For example, in *Uniroyal, Inc. v. United States*, 3 CIT 220, 225, 542 F. Supp. 1026, 1030 (1982), *aff'd*, 702 F.2d 1022 (Fed. Cir. 1983), the court held that imported shoe uppers added to an outer sole in the United States were the “very essence of the finished shoe” and thus the character of the product remained unchanged and did not undergo a substantial transformation. See also *National Hand Tool Corp. v. United States*, 16 CIT 308 (1992), *aff'd*, 989 F.2d 1201 (Fed. Cir. 1993). Similarly, in *National Juice Products Association v. United States*, 10 CIT 48, 61, 628 F. Supp. 978, 991 (1986), the court held that imported orange juice concentrate “imparts the essential character” to the completed orange juice and thus was not substantially transformed into a product of the United States.

For products used in medical-related applications, we have held that no substantial transformation occurs when the critical components which impart the essential character of the product subsequently undergo simple assembly and processing. In HQ H296072, dated July 13, 2018, CBP considered the processing of a subdermal needle electrode. The processing was quite similar to the processing that the electrodes undergo in this case, and included attaching a lead wire to the electrode, adding a heat shrink and protective cover, and packaging. In HQ H296072, the subdermal needle electrodes of U.S. origin were attached by soldering in China. CBP held that the stimulating probes of the subdermal needle electrodes were not substantially transformed by the Chinese processing.

HQ H300744, dated February 20, 2019, concerned the country of origin of various stimulating probes for purposes of U.S. government procurement. The probes were produced in the United States by cutting U.S. origin raw stainless steel rods to specified lengths. After cutting, the rods were ground to a precise diameter on a precision lathe. In China, the steel probes were attached to a lead wire of Korean origin using Chinese solder, and the probes were covered with a heat shrink from China, Japan, or the United States. The probes were attached to a hand grip consisting of a U.S.-origin handle insert and a Korean origin plastic handle. CBP held that the stimulating probes were not substantially transformed by the processing that occurred in China. Although a handle was added to the stimulating probes, CBP noted that the handles were not necessary to the functioning of the probes, but rather only added to their ease of use.

In this case, the product's main function is provided by the EEG cutaneous electrode, which allows for a physical connection between a patient and the medical diagnostic equipment when the electrode is applied directly to a patient's skin to record physiological signals. Attaching the lead wire to the EEG electrode allows the EEG to be used, but the EEG electrode does not lose its individual identity by the simple assembly in China. Consequently, the U.S. cutaneous EEG electrodes, rather than the Korean-origin lead wire, determine the essence of the finished product.

As in HQ H296072 and HQ H300744, the processing in China which involves the attaching of the lead wire by simple assembly through crimping or gluing is a minor operation that leaves the identity of the U.S. made self-adhesive cutaneous EEG electrodes intact. Both the crimping and gluing require only a low level of skill and technology. The crimping process takes roughly five seconds to perform, while the alternative gluing process takes roughly 20 seconds to complete. The remaining processing of the Product, consisting of cleaning and drying (spin and convention drying), adding the heat shrink cover, and inserting the Product into the plastic pouch and cardboard packaging are likewise simple, minor, and low-skill operations. Therefore, we find that the name, character, and use of the cutaneous electrode remain unchanged after the lead wire and other components are attached in China. As such, the U.S. origin cutaneous EEG electrodes which are processed in China by attaching a lead wire and being covered with a heat shrink, are not substantially transformed. Accordingly, for purposes of government procurement, we find that the last substantial transformation of the product is in the United States.

**HOLDING:**

Based on the information provided, the last substantial transformation of the self-adhesive cutaneous EEG electrode product occurs in the United States.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Craig T. Clark  
Acting Executive Director



Regulations and Rulings  
Office of Trade

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